08/089,407 ✓ 07/08/93 LUCIW

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1035.009

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
		HM31/0217	
~~ALISA A. HARGIN~~			~~WOODWARD,M~~

CHIRON CORPORATION
INTELLECTUAL PROPERTY DEPARTMENT-R440
4560 HORTON STREET
EMERYVILLE CA 94608-2916

EXAMINER	
1643	
ART UNIT	PAPER NUMBER
	02/17/98

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on NOVEMBER 26, 1997

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 60-70 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 60-70 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-404-496/47

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1643**.

Applicant's arguments filed November 26, 1997 have been fully considered but they are not persuasive.

Claims 60-70 are rejected under 35 U.S.C. § 112, first paragraph, as the specification fails to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

It is unclear to the examiner how applicant's response addresses the arguments raised in the previous Office Action other than by reiterating arguments which applicant has previously presented and which arguments have been found unpersuasive.

Applicant's response of November 26, 1997 begins with citations to case law concerning enablement. These citations are those previously presented. In response thereto the examiner has directed applicant's attention to *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001-1007 (Fed. Cir. 1997), *In re Jackson*, 217 USPQ, *Ex parte Forman* and *In re Cavallito and Gray*, 127 USPQ 203, (CCPA 1960).

The examiner then proceeded to present an analysis of each of the Forman factors, however, applicant has failed to address each element.

With respect to the citation from *Genentech Inc. v. Novo Nordisk A/S* applicant has offered no argument.

Applicant asserts that the Young declaration should be accorded considerable weight because it "was not merely conclusionary but was based on scientific reasoning and authority." The examiner notes that in the previous Office Action he did not dismiss the declaration as no more than mere conclusion but instead provided a detailed analysis of its deficiencies. Is it unclear how citation of *In re Alton* (37 USPQ2d 1578 (Fed. Cir. 1996)) rebuts the objective analysis presented in the previous Office Action..

In response to the conclusions of paragraph 8 of the Young declaration the examiner pointed out that the art relied upon was ambiguous with regard to retroviral peptides. Applicant takes issue with this analysis and alleges that the examiner has implied that antibodies directed toward retroviral proteins behave differently than those which recognize native proteins. Not really, the examiner merely pointed out what the paragraph spoke to, however, so as to expedite prosecution the examiner accepts that the teachings upon which Young relies are as applicable to retroviral peptides as they are to any other peptide. Similarly, the examiner asserts that applicant also must abide by Young's conclusion. Page, second full paragraph.

Applicant does not controvert the examiner's argument that the claims embrace every synthetic peptide which can be produced from the putative *env* ORF. Applicant asserts that there is no *a priori* requirement that the actual number of species be determinable This is a straw man, since the point the examiner was making in the previous Office Action concerned the breadth of the claims. Applicant is correct that the issue is undue experimentation, however, that this is the issue has never been in dispute as is clearly evident from the record. What has been at issue and remains at issue is what constitutes undue experimentation with

regard to the instantly claimed invention.

Applicant frames the issue as "whether the species could have been identified without 'undue experimentation.'"

If one had a synthetic peptide it is correct that one could easily test, employing the methods described in applicant's specification, whether or not it fell within the scope of applicant's claim.

However, the examiner asserts that what is missing from applicant's specification is the necessary guidance as to which peptide to make so that there would be a reasonable expectation that it would function in the assay methods presented in applicant's specification.

Applicant is claiming compounds on the basis of their function absent teachings of what structural elements are necessary to that function.

Page 3, third paragraph to page 5

Applicant presents argument concerning the number of peptides which would need to be produced so as to obtain a peptide within the scope of the claims. Applicant's argument begs the question of whether or not any of the strategies asserted are described in the specification. Indeed, they are not.

Nor does applicant's argument address the point made by the examiner that the art which Young relies upon to support employing the Hopp algorithm did not employ the Hopp strategy whatsoever.

Page 5. second paragraph.

Applicant concludes his arguments by stating that "one skilled in the art could have made and used the present invention without knowing in advance which synthetic peptide will be antigenic." It is probably true that one skilled in the art could by trial and error experimentation obtain a synthetic peptide within the scope

of the claims. As noted previously, if this is the standard for enablement then applicant's specification is enabling.

Claims 60-70 are rejected under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

Page 8, first paragraph.

Applicant draws the examiner's attention to page 3 of the '501 specification as rebuttal of the examiner's argument that the entire thrust of the '501 specification is to recombinantly produced HIV polypeptides and fragments thereof. The examiner has reviewed page 3 of the '501 specification and finds, as he found before, that the sole reference to synthetic peptides occurs at the end of the summary of the invention. There is nothing in the summary speaking to the employment of synthetic peptides in immunoassays.

At page 8 applicant states:

> The office action concedes that the specification does teach the use of "HIV polypeptides and fragments thereof" in an env based immunoassay.

The examiner has word searched the previous Office Action in an effort to find such a concession. The examiner's search was unsuccessful. Cited below is the sole occurrence of "HIV polyeptides and fragments thereof:"

> Disregarding the issue of immunogenic there is no description in the specification of any of the instantly recited assays nor the now recited polypeptide composition. The entire thrust of applicant's specification and examples is to recombinantly produced HIV polypeptides and fragments thereof. the sole example of an *env* based immunoassay in the '501 and '534

involves recombinant expression from an open reading frame vector containing *env* and approximately 400 bp of additional coding material 5' thereto. This is certainly not a description of an immunoassay or composition containing a synthetic peptide, assuming that synthetic peptide means a solid-phase produced peptide of less than 40 amino acids. Nowhere in the specification is there even passing reference to methods for synthesis of synthetic peptides despite references to art such as "[t]he well-established Southern technique (J Mol Biol (1975) 98:503)" at page 6 of the '501 specification.

It is clear from the cited passage that the examiner is conceding nothing.

Applicant further argues that nothing in the summary of the invention limits the application of its last sentence. Assuming that applicant is correct and that one can remove the sentence from the context in which it occurs one still must have evidence from elsewhere in the specification to support ones position. Applicant fails to provide clues as to where in the specification there is written description and enabling disclosure for immunoassays employing synthetic peptides.

PRIORITY DATE BASED REJECTIONS

Claims 60-70 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Chang et al. (US Patent 4,774,175). See for example claims 2-15.

Claims 60-70 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cosand (US Patent 4,629,783). Cosand describes peptides from the env domain of HIV and their use in solid phase immunoassays for the detection of antibodies present in the sera of patients infected with HIV.

Claims 60-70 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Chang et al. (US Patent 4,774,175) for the reasons of record.

Claims 60-70 are rejected under 35 U.S.C. § 102(e) as being clearly

anticipated by Cosand (US Patent 4,629,783) for the reasons of record.

These rejections will be maintained until such time as applicant overcomes the extant rejections under 35 U.S.C. §112, first paragraph.

Claims 60-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over either the combined teachings of Schupbach et al., Sarngadharan et al. and Popovic et al. or in combination with Levy (US 4,716,102) and in view of the level of skill in the art as set forth in the Young Declaration.

Applicant traverses this rejection by asserting that the examiner ignores the true confusion in the art in 1984 at the time the '501 application was filed. Applicant fails to set forth exactly what is confusing.

With regard to Levy applicant states:

> While Levy professed to have an ARV2 containing cell line, that is a far cry from having the sequence of the genomic sequence or the sequence of the envelope portion of the cell line. Given the confusion in the art, there is no basis to conclude that Popovic and Levy (or any of the other workers) had the same virus or even a closely related virus."

Levy is a US patent which claims the ARV2 containing cell lines. Is applicant questioning the validity of Levy's claims? If so, then applicant is invited to provide evidence in support thereof. In addition, applicant is invited to explain just how applicant obtained ARV2 from the Levy cell line, see the '501 specification. Nor does applicant establish what a far cry is. Presumably applicant is arguing that obtaining the viral genome and sequencing it constitutes undue experimentation. Applicant offers no evidence in support thereof.

Claim 68 is rejected under 35 U.S.C. § 112, first paragraph, as the

specification, as originally filed, does not provide support for the invention as is now claimed.

The specification does not speak to peptides having at least 15 amino acids from the *env* region

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Since the fee set forth in 37 CFR 1.17(r) for a first submission subsequent to a final rejection has been previously paid, applicant, under 37 CFR 1.129(a), is entitled to have a second submission entered and considered on the merits if, prior to abandonment, the second submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a second submission and the appropriate fee under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. If a notice of appeal and

the appeal fee set forth in 37 CFR 1.17(e) were filed prior to or with the payment of the fee set forth in 37 CFR 1.17(r), the payment of the fee set forth in 37 CFR 1.17(r) by applicant will be construed as a request to dismiss the appeal and to continue prosecution under 37 CFR 1.129(a). In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MP Woodward whose telephone number is (703) 308-3890. The examiner can normally be reached on Monday-Friday from 7:30 AM to 5:00 PM. In the event that the examiner does not personally answer the telephone his voice mail will provide the necessary instructions.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311.

Currently a plurality of official and unofficial fax lines are available. However, changes in fax location occur with frequency. Please contact the examiner to obtain the currently operative fax numbers.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL P. WOODWARD
PRIMARY EXAMINER
GROUP 1800

February 14, 1998